UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,273	12/11/2000	Edwin A. Clark	2825.2004-001	3583

21005 7590 09/17/2002

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER
SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
1635	8

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/735,273	CLARK ET AL.	
	Examiner	Art Unit	
	Mary Schmidt	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 23-26, drawn to methods of inhibiting metastasis in a mammal via administering an effective amount of an agent which alters the actin-based cytoskeleton of one or more tumor cells in the mammal, classifiable in class 514, subclasses 2 or 44.

II. Claims 12-19, 27-29 and 35, drawn to methods of predicting the likelihood of development of a metastatic condition in a mammal via determining the amount of gene products in a biological sample from a mammal and comparing the level with a control level, classifiable in class , subclass .

III. Claims 20-22 and 30-34, drawn to methods of identifying an agent which regulates metastasis of a tumor cell via testing test agents for their effect on gene products in the tumor cells, classifiable in class , subclass .

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions: The methods of Group I are drawn to inhibiting metastasis in

a mammal via administering an effective amount of an agent which alters the actin-based cytoskeleton of one or more tumor cells in the mammal; The methods of Group II are drawn to methods of predicting the likelihood of development of a metastatic condition in a mammal via determining the amount of gene products in a biological sample from a mammal and comparing the level with a control level. The methods of Group I depend on the organism already having a metastasis and steps for inhibition of the metastasis whereas the methods of Group II depend on predicting whether or not a mammal will develop a metastasis in the future. The methods thus have divergent and independent functions that do not share the step processes.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions: Group II is drawn to methods of predicting the likelihood of development of a metastatic condition in a mammal via determining the amount of gene products in a biological sample from a mammal and comparing the level with a control level; Group III is drawn to methods of identifying an agent which regulates metastasis of a tumor cell via testing test agents for their effect on gene products in the tumor cells. The methods of Group II depend on predicting whether or not a mammal will develop a metastasis in the future whereas the methods of Group III depend on starting with a tumor cell for testing compounds which effect the metastasis of the tumor cell. The methods thus rely on distinct and independent method steps

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions: The methods of Group I are drawn to inhibiting metastasis in a mammal via administering an effective amount of an agent which alters the actin-based cytoskeleton of one or more tumor cells in the mammal; The methods of Group II are drawn to methods of predicting the likelihood of development of a metastatic condition in a mammal via determining the amount of gene products in a biological sample from a mammal and comparing the level with a control level. The methods of Group I depend on the organism already having a metastasis and steps for inhibition of the metastasis whereas the methods of Group II depend on predicting whether or not a mammal will develop a metastasis in the future. The methods thus have divergent and independent functions that do not share the step processes.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each of Group I, II or III is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. This application contains claims directed to the following patentably distinct species of the claimed invention: the gene that is altered by the agent in the mammal or the tumor cells. Specifically, claims 4, 7, 25 and 26 in Group I, claims 14 , 15, 28 and 29 in Group II, and claims 21, 22, and 31-34 specify patentably distinct genes for detection/measurement in the claimed methods. Applicant is required to elect one gene in the elected Group. Please note that if a gene other than RhoC is elected, the claims specifying only detection/measurement of RhoC (claims 7 and 26 in Group I (and similarly, claim 25 which specifies three types of genes), claims 15 and 29 in Group II, and claims 22 and 32-34 in Group III) will not be examined on the merits if drawn to the non-elected gene species. Applicant is advised that should a gene other than RhoC be elected, for instance, that those claims currently drawn to a gene other than RhoC should be amended so that they are drawn to the elected gene species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 8-11 and 23-26 are generic in Group I; claims 12-14, 16-19, 27-28, and 35 are generic in Group II; and claims 20-21 and 30-31 are generic in Group III.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Furthermore, should Group I be elected above, the following restriction is required of claims 10 and 11 within Group I:

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10 and 11, wherein the agent is an organic molecule that is a nucleic acid molecule such as an antisense, classifiable in class 514, subclass 44.

II. Claim 10, wherein the agent is an organic molecule that is an antibody, classifiable in class 514, subclass 2.

III. Claim 10, wherein the agent is an organic molecule that is a peptide, classifiable in class 514, subclass 2.

IV. Claim 10, wherein the agent is an organic molecule other than a nucleic acid, antibody, or protein/peptide, classifiable in class 514, subclasses 2 or 44.

V. Claim 10, wherein the agent is an inorganic molecule, classifiable in class, subclass .

6. The inventions are distinct, each from the other because of the following reasons:

7. The agents of Group I, claims 10-11 are drawn to nucleic acid, protein/peptide, antibody, other organic molecules and inorganic molecules respectively. These inventions are distinct because they have different chemical, physical, and functional properties as evidenced by divergent classification, process of making and process of using. These products are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art). For instance nucleic acids are composed of nucleotide bases that are distinct from the amino acids in proteins and antibodies, and the metals of the inorganic molecules. Antibodies are considered distinct proteins from other peptides and proteins because of their unique structure and classification that is divergent from the protein structure of receptor proteins for example.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
September 13, 2002